PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13

In re application of : Nancy Chang et al.

Serial No. : 06/659,339

Filed : October 10,1984

For : CLONING AND EXPRESSION OF HTLV-III DNA

Assistant Commissioner for Patents
Washington, D.C. 20231

RENEWED PETITION UNDER 37 C.F.R. §1.182

Sir:

Attached is a REQUEST FOR RECONSIDERATION OF THE MARCH 29, 1996 DECISION DISMISSING APPLICANTS' PETITION PURSUANT TO 37 C.F.R. §1.182 TO ADD A REFERENCE TO A PRE-FILING DATE DEPOSIT.

The Assistant Commissioner is hereby authorized to charge any additional fees which may be required in this application, including a petition fee, to Deposit Account No. 13-4500, Order No. 1436-4094. A DUPLICATE COPY OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,

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REQUEST FOR RECONSIDERATION OF THE MARCH 29, 1996 DECISION DISMISSING APPLICANTS' PETITION PURSUANT TO 37 C.F.R. §1.182 TO ADD A REFERENCE TO A PRE-FILING DATE DEPOSIT

Sir:

Applicants respectfully request reconsideration of the March 26, 1996 decision dismissing their petition to insert a reference to the pre-filing date deposit of a recombinant phage clone harboring HTLV-III DNA, λBH-10, which is specifically identified in the specification of U.S.S.N. 06/659,339.[1]

Applicants' submit that for the reasons set forth below and those in their petition filed February 20, 1996, amendment of U.S.S.N. 06/659,339, now abandoned, to add the reference to the deposit is appropriate pursuant to the governing case law, the

[1] Applicants' agree with the decision to grant their petition to insert a reference under 35 U.S.C. 120 to application No. 06/643,306, filed August 22, 1984. Thus, reconsideration of this part of the decision is not sought.

Patent and Trademark Office ("PTO") rules regarding deposit of biological materials, 37 C.F.R. §§1.801-1.809, and the Manual of Patent Examining Procedure ("MPEP").

REASONS FOR RECONSIDERING THE DECISION AND GRANTING THE PETITION

Applicants respectfully submit that two positions taken in the March 29, 1996 Decision (the "Decision") are not supported by either the PTO rules and procedure or Federal Circuit precedent. Thus, they should be reconsidered.

1. Addition Of A Reference To A Deposit Is Proper Where The Biological Material Is Specifically Identified In The Specification As Filed

First, Applicants respectfully submit that, contrary to the position in the Decision (pp. 8-10), there is no requirement in either the PTO rules or examining procedure or In re Lundak, 773 F.2d 1216 (Fed. Cir. 1985) that a specification as filed must refer to a deposit of a biological material in order to add a reference to the date, depository name and accession number of the deposited material. Indeed, the deposit rules, 37 CFR §§1.801-1.809, and the MPEP make clear that a post-filing date deposit may be made and/or a reference to deposit data added as long as the biological material was specifically identified in the Application as filed. The PTO rules state:

> Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for

> patent or, subject to §1.809, during pendency of the application for patent.

37 CFR §1.804(a) (emphasis added). See also 37 CFR 1.809(d) There is no requirement that the deposit be referenced in the specification. As the MPEP explains:

> 37 CFR 1.804(a) specifies not only a permissible time frame for making an original deposit, but also specifies that the biological material deposited must be specifically identified in the application as filed. The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 USC 112 and provides an antecedent basis for the biological material which either has been or will be deposited before the patent is granted.

MPEP §2406.01 (emphasis added). Thus, while the biological material must be identified and referenced in the specification, the existence of a deposit need not be mentioned.

Indeed, the MPEP specifically distinguishes between the permissible addition of a reference to a deposit of an identified biological material and the impermissible addition of a reference to the biological material itself, which is prohibited as new matter under 35 USC §132:

> It should be noted, however, that reference to a biological material present in an application upon filing, may form the basis for making a deposit, where required, after the filing date of a given application, but that the reference to the biological material itself, cannot be added after filing without risking the prohibited introduction of new matter.

35 USC §132. MPEP §2404.03

In the instant situation, Applicants seek only to add a reference to the pre-filing date deposit of a biological material, clone λBH-10, which was specifically identified in the specification as filed. Indeed, as discussed in the attached Amendment and Declaration of Dr. Flossie Wong-Staal ("Wong-Staal Declaration", attached as Ex. 1), λBH-10 clones, which were referred to in the '339 specification as "lambda 10 clones" were specifically identified and described in the '339 specification on page 3, lines 28-30, page 8, lines 33 to page 9, line 1, and page 9, lines 3-8 of the '339 application as filed. Additionally, restriction maps of clone λBH-10, showing restriction enzyme sites present in this clone are found at Figs. 1a, 1b and 2 of the '339 application as filed. See Declaration of Dr. Wong-Staal, ¶10.

Moreover, Dr. Wong-Staal's declaration makes clear that the λBH-10 clones deposited more than two months before the filing date of the '339 application are the same as those identified and described in the '339 specification. Finally, the Wong-Staal declaration and Amendment establish that the deposit of clone λBH-10 was made in full compliance with the deposit rules of the PTO, 37 CFR §§1.801-1.809. See Wong-Staal Decl., ¶¶5-8. See also Amendment, pp. 3-5, attached as Ex. 2. Thus, pursuant to 37 CFR §1.802, 1.804 and 1.809(d) and MPEP §§2406.01 and 2404.03, amendment of the '339 specification to include a reference to the deposit of clone λBH-10 is proper.

Applicants note that the Decision appears to interpret the Lundak case to authorize addition of deposit data to a specification only where the deposit itself was referenced in the specification. Applicants' respectfully submit that this is an improperly narrow interpretation of Lundak. As discussed above, such an interpretation would be contrary to the deposit rules and the MPEP. Additionally, the issue before the Federal Circuit in Lundak was not whether Lundak could "update" or "clarify" his deposit data. Rather, as the Federal Circuit noted, the PTO had argued "that a post-filing deposit is barred as new matter, as is the insertion into the specification of reference to such deposit." 773 F.2d at 1222. The Federal Circuit rejected this argument, holding that "the insertion of depository data after filing is not new matter under 35 USC §132." Thus, Applicants respectfully submit that it is improper to interpret Lundak to authorize only the clarification or updating of deposit data.

2. Addition Of The Reference To The Deposit Is Not New Matter Under 35 USC §132

Second, Applicants respectfully submit that the position taken in the Decision (p. 9-11), that amendment of the '339 specification is improper because it may constitute new matter and thus be precluded by 35 USC §132, is contrary to the controlling law.

In In re Lundak, 773 F.2d 1216 (Fed. Cir. 1985), the Federal Circuit was faced with the issue of whether a post-filing date deposit of a biological material and amendment of the

specification to reference such deposit was new matter under 35 USC §132. The court concluded that the post-filing date deposit was proper and that "the insertion of deposit or data after filing is not new matter under 35 USC §132." Lundak, 773 F.2d at 1223 (emphasis added). The court explained:

> An accession number and deposit date add nothing to the written description of the invention. They do not enlarge or limit the disclosure. This is not the shape of new matter against which section 132 was designed to guard.

Lundak, 773 F.2d at 1223 (emphasis added). See also MPEP §2406.01. ("The [Lundak] court further held that the addition of information designating the depository, accession number, and deposit date of the deposited cell line in ATCC after filling date did not violate the prohibition against new matter in 35 USC 132.")

In light of the Federal Circuit's explicit holding that addition of a reference to a post-filing date deposit does not constitute new matter, Applicants respectfully submit that addition of a reference to the deposit of clone λBH-10, made two months before the filing date, cannot be considered new matter.

Applicants note that, based on a decision in Chiron v. Abbott Laboratories, Civil Action No. 93-4380 MHP, reported at 902 F. Supp. 1103 (N.D. Cal. 1995), the Decision questioned whether the '339 specification satisfied the enablement and best mode requirements of 35 USC §112. Applicants respectfully submit that reliance on the decision in the Chiron v. Abbott litigation is improper for several reasons. First, neither Applicants nor their

assignees (Centocor, Inc. and the National Institutes of Health) are parties to this action. Consequently, Applicants had no opportunity to be heard or to defend against Chiron's allegations regarding their specification. Thus, any decision in the Chiron-Abbott litigation cannot be res judicata as to Applicants, nor may it preclude or estop Applicants from defending their applications. Additionally, as stated in the opinion of the Northern District of California Court, the Judge considered the record before her "quite weak" and made her decision without benefit of expert testimony on these issues.

Second, the issue of whether the '339 application is enabling without reference to the deposit of clone λBH-10 is irrelevant to the instant petition. 37 CFR §1.802(b) states that "[i]f a deposit is necessary, it shall be acceptable if made in accordance with these regulations." As discussed supra, section 1, the deposit of clone λBH-10 was made in full compliance with the deposit rules, which do not require proof that a specification is enabling without the deposit as a prerequisite for allowing the post-filing date addition of a reference to a deposit.[2] Moreover, the discussion in Lundak about whether the specification as filed was enabling was necessitated by Lundak's appeal of the rejection

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[2] Indeed, 37 CFR §1.802(c) states:

> The reference to a biological material in a specification disclosure or the actual deposit of such material by an applicant or patent owner does not create any presumption that such material is necessary to satisfy 35 USC 112 or that deposit in accordance with these regulations is or was required.

of his claims under 35 USC §112, not because it was a requirement to allow the addition of a post-filing date reference to his specification. See e.g., 773 F.2d at 1220.

Because the deposit of λBH-10 is in full compliance with the governing law and the addition of a reference to the pre-filing date deposit of λBH-10 "is not the shape of new matter against which section 132 was designed to guard," Lundak, 772 F.2d at 1223, Applicants respectfully submit there is no need to examine the '339 application for new matter, and thus, 35 USC 132 does not bar entry of this amendment.[3] Indeed, Applicants submit that the proposed amendment is akin to the request to add a section 120 reference previously allowed by the Office of Petitions and is fully within the scope of amendments authorized by Sampson v. Commissioner of Patents, 195 U.S.P.Q. 136 (D.D.C. 1976).[4] As such, Applicants respectfully request that the amendment be entered.

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[3] Contrary to the Decision at p. 8, Applicants are not seeking "to change the invention disclosed or to introduce a concept not previously present in the specification of an abandoned application or to continue prosecution of an abandoned application". Rather, Applicants are seeking to add the depository data for an HIV clone which was specifically identified in the specification as filed and was deposited two months prior to the filing date. See Wong-Staal Decl. ¶¶ 4, 10. As discussed supra, in view of the PTO rules and procedure and Federal Circuit precedent, such an amendment is not new matter and does not require examination under 35 U.S.C. §132.

[4] Applicants respectfully submit that Dart Industries, Inc v. Banner, 636 F.2d 684, 687-688 (D.C. Cir. 1980), cited in the Decision at p. 10, is inapposite because reference to a biological material specifically identified in the specification is not new matter under Lundak and the PTO Deposit rules.

CONCLUSION

Applicants respectfully request that the March 29, 1996 Decision be reconsidered and that the petition be granted and the amendment to the '339 application be entered to protect Applicants' patent rights.

AUTHORIZATION

The Assistant Commissioner is hereby authorized to charge any additional fees which may be required in this application, including a petition fee, to Deposit Account No. 13-4500, Order No. 1436-4094.

Respectfully submitted,

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In re application of: Nancy Chang et al.

Serial No. : 06/659,339

Filed : October 10, 1984

For : CLONING AND EXPRESSION OF HTLV-III DNA

Assistant Commissioner for Patents
Box DAC
Washington, D.C. 20231

DECLARATION OF FLOSSIE WONG-STAAL, Ph.D.

I, Dr. Flossie Wong-Staal, hereby declare:

1. I am an inventor of the subject matter described and claimed in the above-referenced application.

2. My educational background and professional and research experience are listed in my curriculum vitae, attached as Ex. A.

3. In July 1984, I deposited a recombinant phage clone harboring HTLV-III DNA, designated λBH-10, with the American Type Culture Collection ("A.T.C.C."), 12301 Parklawn Drive, Rockville, MD 20852.

4. The A.T.C.C. filing receipt, attached as Exhibit B, shows that the deposit was received and accepted by the A.T.C.C. on July 30, 1984. The accession number of clone λBH-10 is 40125.

5. The A.T.C.C. filing receipt certifies that the A.T.C.C. is an International Depository Authority established

under the Budapest Treaty and that the deposit was made under the Budapest Treaty.

6. The A.T.C.C. filing receipt also states that clone λBH-10 will be maintained for a period of at least 30 years from the deposit date and at least 5 years after the most recent request for a sample.

7. The A.T.C.C. filing receipt certifies that clone λBH-10 will be made available if "a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. patent is issued citing" λBH-10. Additionally, the A.T.C.C. filing receipt states that the viability of clone λBH-10 has been tested and confirmed.

8. The λBH-10 clone deposited on July 30, 1984 was specifically identified, described and characterized in U.S.S.N. 06/659,339 ("the '339 application"), as filed, on October 10, 1984.

9. In the '339 specification we used the short-hand or abbreviated phrases "lambda$_{10}$ clones" or "λ_{10}" to refer to the λBH-10 clone. This nomenclature refers to the fact that HTLV-III molecular clone BH-10 had been inserted into bacteriophage lambda.

10. The '339 specification, attached as Exhibit C, identifies clone λBH-10 and describes its uses and characterization. For example, the '339 specification states that in one embodiment of the invention, "lambda$_{10}$ clones harboring HTLV-III DNA are cloned from the replicated virus."

(page 8, line 33 to page 9, line 1). Similarly, the '339 specification also describes the characterization of the λBH-10 clone (designated in "λ_{10}" Figures 1a and 1b) at page 9 of the text:

> Cuts are made in the cloned HTLV-III DNA with the restriction enzyme Sst I. (Figure 1a) Because there are two Sst I recognition sites within the LTR of HTLV-III DNA, one LTR region is not present in the cloned DNA sequence removed from the lambda$_{10}$ vector . . . .

(page 9, lines 3-8). The restriction maps presented in Figs. 1a, 1b and 2 of the '339 application further characterize clone λBH-10. Moreover, as described in the '339 specification, we used clone λBH-10 to express and screen recombinantly-produced HTLV-III proteins. See e.g., page 12, lines 1-5 and 11-14.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 to Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 5/14/96

Flossie Wong-Staal, Ph.D.

116. Wong-Staal, F. and Haseltine, W.A.: Regulatory genes of human immunodeficiency viruses. Mol. Genet. Med. 2: 198-219, 1992.

117. Kurth, R. and Wong-Staal, F.: AIDS 92/93, Virology: Overview. AIDS 7 Suppl 1:S1-2:s1-2, 1993.

118. Walfield, A.M., Li, L.M., Hosein, B., Wang, C.Y, Looney, D.J., and Wong-Staal, F.: High-titer neutralization of multiple HIV-1 isolates by radically branched immunogens. In: Koff, W., Kennedy, R., and Wong-Staal, F. (Eds.) Annual Review in AIDS, Vol. 3, pp. 345-360, 1993.

119. Poeschla, E. and Wong-Staal, F.: Molecular Biology of HIV: Challenges for the second decade. Tenth Anniversary Perspectives on AIDS. AIDS Res. Human Retro. 10:111-112. 1993.

120. Wong-Staal, F.: AIDS Research: A five-year perspective. J. of NIH Res. 6: 70-73, 1994.

121. Yu, M., Poeschla, E., and Wong-Staal, F.: Progress towards gene therapy for HIV infection. Gene Therapy 1: 13-26, 1994.

122. Poeschla, E. and Wong-Staal, F.: Antiviral and anticancer ribozymes. Curr. Opin. Oncol. 6: 601-606, 1994.

123. Poeschla, E. and Wong-Staal, F.: Gene therapy and HIV disease. In: Volberding, P. and Jacobson, M.A. (Eds.): AIDS Clinical Review, Marcel Dekker, Inc., New York, pp. 3-45, 1995.

124. Wong-Staal, F.: Ribozyme gene therapy for HIV infection: Intracellular immunization of lymphocytes and CD34+ cells with an anti-HIV-1 ribozyme gene. Advanced Drug Delivery Reviews, vol. 17, pp. 363-368. Elsevier, The Netherlands, 1995,.

125. Wong-Staal, F.: Development of ribozyme gene therapy for HIV infection. Antibiotics and Chemotherapy, Karger, Switzerland, in press.

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Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

AMENDMENT

In The Specification

Please amend p. 1 of the specification to read as follows:

insert - This application is a continuation-in-part of U.S. application Serial No. 06/643,306, filed August 22, 1984. - in a new paragraph after the title.

Please amend p. 3, line 30 of the specification to read as follows:

insert - A recombinant phage clone harboring HTLV-III DNA, designated λBH-10, was deposited with the American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD, 20852 on July 30, 1984 under ATCC accession number 40125. -

Start new paragraph with "In one embodiment,...."

REMARKS

Applicants are seeking to make two amendments to this application.

A. The Section 120 Specific Reference

First, pursuant to 35 U.S.C. § 120, Applicants are adding a specific reference to application Serial No. 06/643,306 ("the '306 application"). The '306 application describes the cloning of HTLV-III from an immortalized human T-cell line, and preparation of a HTLV-III clone used in the '339 application. The '306 application was filed by two inventors common to this application, Drs. Gallo and Wong-Staal, and was co-pending with this application.[1] The '306 application was subsequently re-filed as a continuation application, Serial No. 07/033,891, filed April 3, 1987, now abandoned; continuation-in-part application Serial No. 07/160,827, filed February 26, 1988, now abandoned; continuation application Serial No. 07/832,603, filed February 12, 1992, now

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[1] As filed, the '339 application listed Dr. Nancy Chang as the sole inventor. On May 14, 1986 petitions to change the inventorship to add Dr. Robert Gallo and Dr. Flossie Wong-Staal were filed in the '339 application and in U.S.S.N. 06/693,866, the continuation in part application filed on January 23, 1985. Apparently, the '339 application was abandoned before the petition to change inventorship was acted upon. However, in Paper No. 13, issued November 27, 1987, the PTO examiner changed the inventorship of the '866 application to include Drs. Gallo and Wong-Staal. Pursuant to the Weil v. Fritz, 572 F.2d 856 (C.C.P.A. 1978) and In re Schmidt, 293 F.2d 274 (C.C.P.A. 1961) decisions, amendment of the '866 application was legally effective to change the inventorship of the '339 application. Thus, Drs. Chang, Gallo and Wong-Staal are the legal inventors of the '339 application.

abandoned and currently pending continuation application, Serial No. 08/385,231, filed February 8, 1995, (collectively "the '306 family of applications").

The law is well developed that an abandoned application can be amended to add a specific reference under 35 U.S.C. § 120. Sampson v. Commissioner of Patents, 195 U.S.P.Q. 136 (D.C. D.C. 1976). Thus, the amendment of this application to add the specific reference under section 120 is appropriate.

B. The Deposit Reference

The second amendment is the insertion of a reference to the pre-filing date deposit of a molecular clone of HTLV-III referred to in the specification. This deposit, accepted by the ATCC on July 30, 1984, is also referenced in the '306 application and the '306 family of applications. Pursuant to the authority of In Re Lundak, 773 F.2d 1216 (Fed. Cir. 1985), the reference to the deposit is appropriate.

Specific reference to the deposited clone is found at the following locations in the application:

The '339 application describes the "cloning of HTLV-III DNA in recombinant/vector host systems capable of expressing immunoreactive HTLV-III polypeptides" (p.3, 28-30).

The '339 application discusses as an embodiment of the invention that "lambda $_{10}$ clones harboring HTLV-III DNA are cloned from the replicated form of the virus" (p. 8, 33 to p. 9, 1). In the '339 application as originally filed, the nomenclature "lambda

$_{10}$ clones" refers to the recombinant phage clone BH10. The nomenclature designates the HTLV-III molecular clone BH10 inserted into bacteriophage lambda, which was used in expression of HTLV-III polypeptides and expression screening. As used in the '339 application, "lambda $_{10}$ clones" represents an abbreviated or short-hand nomenclature for lambda BH10 or λBH10 recombinant phage clones harboring HTLV-III DNA of the molecular clone BH10 in bacteriophage lambda (See attached Chang Exhibit 13, B.H. Hahn et al., 1984, Nature, **312**:166-169, p.167 and Figure 2).

The '339 application also describes the characteristics of the lambda BH10 clone, designated "λ_{10}" in Figs. 1a and 1b, at p. 9, 3-8:

> Cuts are made in the cloned HTLV-III DNA with the restriction enzyme SstI. (Figure 1a) Because there are two SstI recognition sites within the LTR of HTLV-III DNA, one LTR region is not present in the cloned DNA sequence removed from the lambda$_{10}$ vector...

For HTLV-III protein expression, the phage lambda gt11 is used as described and taught in the '339 specification at p. 12, 1-5 and 11-14: "The EcoRI linker ligated [HTLV-III] DNA is then treated with EcoRI... and cloned in an expression vector, [λ]gt11". (p. 12, 1-5). In addition, it is disclosed that "AIDS patient serum was used to probe the gt11 library of HTLV-III genomic DNA..." (p. 12, 11-14).

The restriction maps presented in Figs. 1a, 1b, and 2 of the '339 application show restriction enzyme sites in the genome of molecularly cloned HTLV-III which correspond to the genomic restriction enzyme map of clone BH10 depicted in Fig. 2 of the '306 family of applications.

Further, inventor Nancy Chang attested to the fact that bacteriophage lambda containing HTLV-III DNA of the genomic clone BH10 (i.e., lambda BH10 or λ_{BH10}) was used in the HTLV-III cloning and expression work described in the '339 application (See attached Chang Affidavit Exhibit 2, Declaration of Nancy T. Chang, dated February 23, 1986, which accompanied the Petition to Correct Inventorship, filed May 14, 1986 in the '339 application of Chang et al.). In this Declaration, Chang stated that

> [t]he experimental work described in the application began at Centocor upon receipt of genomic HTLV-III DNA from the laboratories of Dr. Gallo and Dr. Wong-Staal. Dr. Gallo and Dr. Wong-Staal supplied a recombinant phage (designated λ_{BH10}) consisting of the genomic HTLV-III cDNA recombined with a phage vector. The HTLV-III cDNA insert was excised from λ_{BH10} and fragmented[,] and the subgenomic fragments were cloned and expressed in host cell systems as described in the application.

(Chang Affidavit Exhibit 2, Chang Declaration, p. 2, ¶4). This statement is supported by the '339 application disclosure at p. 8, 32-33 to p. 9, 1-8.

The ATCC deposit receipt for recombinant clone λBH10, received on July 30, 1984 is submitted as Chang Documentary Exhibit 12. The receipt establishes full compliance with the depository rules of the Patent Office.

Since the '339 application is abandoned, applicants have submitted herewith a petition under Rule 1.182 for entry of the amendments.

CONCLUSION

Entry of the amendments is requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: the Assistant Commissioner for Patents, Washington, D.C., 20231, on February 20, 1996.

Dated: February 20, 1996 By: Eugene Moroz

Eugene Moroz